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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

UNITED STATES OF AMERICA,)	Case No. CR-18-00258-EJD
)	
Plaintiff,)	MS. HOLMES' MOTION TO EXCLUDE
)	EXPERT TESTIMONY OR, IN THE
v.)	ALTERNATIVE, COMPEL ADEQUATE RULE
)	16 DISCLOSURE
ELIZABETH HOLMES and)	
RAMESH "SUNNY" BALWANI,)	Date: July 20, 2020
)	Time: 1:30 p.m.
Defendants.)	CTRM: 4, 5th Floor
)	
)	Hon. Edward J. Davila
)	
)	

MOTION TO EXCLUDE EXPERT TESTIMONY
OR IN THE ALTERNATIVE COMPEL ADEQUATE RULE 16 DISCLOSURE
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NOTICE OF MOTION

PLEASE TAKE NOTICE that on July 20, 2020, at 1:30 p.m., or on such other date and time as the Court may order, in Courtroom 4 of the above-captioned Court, 280 South 1st Street, San Jose, CA 95113, before the Honorable Edward J. Davila, Defendant Elizabeth Holmes will and hereby does respectfully move the Court pursuant to Rule 16 of the Federal Rules of Criminal Procedure for an order excluding the testimony of certain of the government's disclosed experts, or in the alternative, compelling the government to provide an adequate Rule 16 disclosure by August 11, 2020. The Motion is based on the below Memorandum of Points and Authorities and Exhibits, the Declaration of Amy Mason Saharia, the record in this case, and any other matters that the Court deems appropriate.

DATED: July 2, 2020

/s/ Amy Mason Saharia
KEVIN DOWNEY
LANCE WADE
AMY MASON SAHARIA
KATHERINE TREFZ
Attorneys for Elizabeth Holmes

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MEMORANDUM OF POINTS AND AUTHORITIES

Pursuant to Federal Rule of Criminal Procedure 16, the government has disclosed summaries of the expert testimony of several medical professionals from whom it intends to elicit expert opinions regarding Theranos' tests. For four of the government's witnesses—Drs. Steven Linnerson, Audra Zachman, Edward Szmuc, and John Couvaras—the government intends to elicit opinions on hCG (pregnancy) tests. For the other witnesses—JoEllen Embry, Dr. Gerald Asin, and Dr. Curtis Page—the government intends to elicit testimony about various Theranos tests.¹ Each apparently had patients who received Theranos tests during the period of the charged conspiracy.

The government seeks to elicit testimony from these medical professionals about blood tests in general, specific patient tests, and the accuracy of Theranos test results, all with the imprimatur of medical expertise. But the government's expert disclosure fails to meet the most basic requirements of Rule 16(a)(1)(G). Under Rule 16, the government must summarize the proffered opinion and identify the bases of and reasons for those opinions. The government's summaries violate these requirements in two respects. First, for two experts, the government's summaries disclose topics of expert testimony without summarizing the content of the testimony. Second, for almost all the experts, the government has not disclosed the bases of and reasons for certain opinions, leaving Ms. Holmes to guess what the foundation is for those opinions. Because the government's disclosure fails to meet these requirements, the Court should exclude this testimony or, at a minimum, compel adequate summaries.

ARGUMENT

Rule 16 governs the government's disclosure obligations. Rule 16(a)(1)(G) requires the government to provide "a written summary of any testimony that the government intends to use under Rules 702, 703, or 705 of the Federal Rules of Evidence during its case-in-chief at trial." "The summary provided . . . must describe the witness's opinions, the bases and reasons for those opinions, and the

¹ The government also noticed an additional expert, Dr. Govind Acharya. Declaration of Amy Mason Saharia ("Saharia Decl."), Ex. A at 4. However, the government did not include Dr. Acharya on the witness list it served on Friday, June 26. Ms. Holmes therefore is not moving to exclude his testimony at this time.

witness's qualifications." Fed. R. Crim. P. 16(a)(1)(G). This requirement "is intended to minimize surprise that often results from unexpected expert testimony, [to] reduce the need for continuances, and to provide the opponent with a fair opportunity to test the merit of the expert's testimony through focused cross-examination." Fed. R. Crim. P. 16 advisory committee's note to 1993 amendment.

The summary of the "bases and reasons must be sufficient to allow counsel to frame a *Daubert* motion (or other motion *in limine*), to prepare for cross-examination, and to allow a possible counter-expert to meet the purport of the case-in-chief testimony." *United States v. Cerna*, 2010 WL 2347406, at *1 (N.D. Cal. June 8, 2010). "The summary of bases relied upon by the expert should cover not only written and oral reports, *tests*, reports and investigations, but *any information* that might be recognized as a legitimate basis for an opinion under Federal Rule of Evidence 703" *Id.* (emphases added) (internal quotation marks omitted). Where a witness is "so generic and routine that the testimony will be largely predictable, a shorthand summary of the witness's qualifications and testimony may be adequate." *Id.* (internal quotation marks omitted); *see also United States v. Caputo*, 382 F. Supp. 2d 1045, 1049 (N.D. Ill. 2005) ("The level of detail of this summary depends on the complexity of the expert testimony."). But in all cases, "Rule 16 requires that the government summarize each specific opinion to be offered along with the basis for it." *United States v. Cervantes*, 2015 WL 7734281, at *2 (N.D. Cal. Dec. 1, 2015).

The government's scant summaries—which involve complex medical opinions and not "generic" expert testimony—flunk this standard. After the government served its summaries on March 6, the defense three times requested that the government disclose the witnesses' opinions and the bases and reasons for their opinions. *See Saharia Decl., Ex. B.* (3.12.2020 Letter from K. Trefz to government); *Saharia Decl., Ex. C.* (4.8.2020 E-mail from K. Trefz to government); *Saharia Decl., Ex. D.* (5.6.2020 Letter from K. Trefz to government). The government ignored the first two requests. Two months following the first request, the government finally responded on May 14 that its disclosures "are more than sufficient" and refused to provide any additional information. *Saharia Decl., Ex. E.* (5.14.2020 E-mail from R. Leach to defense counsel).

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The government's summaries have two glaring deficiencies: (1) for two of its witnesses, Dr. Asin and Dr. Page, the government has not even summarized the content of their testimony; and (2) for certain opinions of almost all its witnesses, it has not disclosed the bases of and reasons for those witnesses' opinions.

I. The Government Fails To Describe Dr. Asin's and Dr. Page's Testimony.

First, with respect to Dr. Asin and Dr. Page, the government's disclosure identifies certain potential *topics* of testimony but does not actually summarize the testimony. In particular:

- The government's summary for Dr. Asin states that he will testify about "PSA tests, diabetic tests, protein and calcium tests, and HIV tests," but fails to preview his testimony (or opinion) regarding diabetic, protein, and calcium tests. The summary is completely silent as to what he will say about these tests. For the PSA test, the summary explains that, hypothetically, a doctor may need to order a painful procedure if the test results are high, but it does not explain whether he has an opinion about any Theranos PSA test, let alone what that opinion is. Saharia Decl., Ex. A at 4.
- The summary for Dr. Page states that he will testify about A1C and CBC tests, but does not identify the content of any testimony regarding the CBC test, much less the bases and reasons for any opinion about that test. *Id.* at 6. As with Dr. Asin, the government's summary is completely silent with respect to what Dr. Page will say about CBC tests.

Courts in this District have strictly enforced the requirements of Rule 16. *See Cerna*, 2010 WL 2347406, at *4; *see also United States v. Yagi*, 2013 WL 10570994, at *15-16 (N.D. Cal. Oct. 17, 2013). In *Cerna*, for example, the district court found that a summary that stated that an expert would "testify regarding MS-13 tattoos, symbols, codes, colors and graffiti, and how they are used to communicate" violated Rule 16 because it failed to identify the expert's *opinions* regarding those topics. *Cerna*, 2010 WL 2347406, at *4. Similarly, the court found that a disclosure that an expert would testify that she participated in the examination of a stolen car, and helped collect gunshot residue and forensic evidence

1 from the vehicle, violated Rule 16 because the summary failed to “specify what opinions [the expert]
2 will offer, much less the evidence taken from the [car] about which she will be testifying.” *Id.*

3 The same is true here. The government disclosed that Dr. Asin will testify about diabetic,
4 protein, and calcium tests, Saharia Decl., Ex. A. at 4, but failed to “provide[] any indication of [Dr.
5 Asin’s] actual opinions regarding those subjects, much less any bases and reasons.” *Cerna*, 2010 WL
6 2347406, at *4. The disclosure does not even state *which* diabetic tests or protein tests will be the
7 subject of his expert testimony. The government takes the same approach with Dr. Page, referencing
8 CBC tests in its summary without disclosing any opinion or testimony as to those tests. Saharia Decl.,
9 Ex. A. at 6. These summaries provide “no clue as to what [the witnesses’] opinions would be regarding”
10 those Theranos tests. *See Cerna*, 2010 WL 2347406, at *4. They do not identify, for example, whether
11 the doctors will provide opinions regarding the nature of those tests, error rates, or specific Theranos test
12 results—much less the bases of any such opinions. And the government’s interview memos for these
13 witnesses do not shed further light on what these opinions might be or their bases: Dr. Page’s indicates
14 that he ordered CBC tests from Theranos but had no issues with any test other than HbA1C; Dr. Asin’s
15 suggests that he suspected some issues with undefined diabetic, protein, and calcium tests, but the
16 summary notably excludes those potential opinions while at the same time reasserting his PSA- and
17 HIV-related opinions identified in his interview. Saharia Decl., Ex. F. at 2 (Page 302); Saharia Decl.,
18 Ex. G at 1-2 (Asin 302).

19 Complying with Rule 16 should not be difficult. The government must disclose what these
20 experts’ opinions are regarding Theranos’ tests and identify the specific reasons for and bases of these
21 experts’ opinions—including the medical reasons why they believed that certain tests were inaccurate,
22 the test results on which they based that belief, and the identities of the patients at issue. It does not
23 suffice to say that these witnesses will testify about various tests, leaving the defense to guess what the
24 substance of that testimony will be. Because the government has failed to identify these witnesses’
25 opinions, its summaries for these witnesses violate Rule 16.

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II. The Government Fails To Identify the Bases and Reasons for Certain Opinions by Dr. Asin, Dr. Page, Dr. Zachman, Ms. Embry, Dr. Linnerson, and Dr. Szmuc.

Second, for six of the witnesses, the government has not disclosed the bases and reasons for several of their opinions:

- Dr. Asin’s summary discloses that he will testify about the consequences of a high PSA test result. Saharia Decl., Ex. A. at 4. It also states that he will testify that “an HIV test result showing that it was reactive for HIV 1+2 antibodies, but non-reactive for HIV 1 antibody and HIV 2 antibody, separately, did not make any sense.” *Id.* To the extent these abstract opinions are based on actual Theranos test results, the summary does not identify the test results or patients.
- The government has disclosed that Dr. Page will testify that “he experienced a high quantity of abnormal A1C tests with Theranos testing” and “he did not understand how Theranos could not have known they had a problem with A1Cs for a couple of months.” *Id.* at 6. But the summary does not include the basis of or reason for these opinions; for example, it does not identify the results of the supposedly abnormal tests, describe what was abnormal about them, or identify the at-issue patients. As a result, Ms. Holmes cannot prepare to cross-examine Dr. Page on this issue.
- The summary for Dr. Zachman states that she will testify that she “has never had any other problems with hCG tests aside from the experience she had with her patient who was tested by Theranos.” *Id.* at 2. The summary provides no bases of or reasons for this testimony.
- The summary for Ms. Embry states that she will testify that “in 20-plus years of using Sonora Quest and LabCorp, she has never experienced any clinical errors with their lab results.” *Id.* at 3. The summary provides no bases of or reasons for that contention. Similarly, the summary states that Ms. Embry will testify that “to this day she has never had any patients with testosterone as low as what Theranos was reporting.” *Id.* The summary, however, does not identify any specific patients or the actual test results about which she intends to testify.

Without such information, the defense cannot prepare to cross-examine Ms. Embry.

- 1 • The government’s summary for Dr. Linnerson explains he will testify that “[h]is practice has
2 never had problems with its hCG tests with other established laboratories before it started
3 using Theranos.” *Id.* at 2. The summary provides no bases of or reasons for that opinion.
4 The summary also states that “if a Theranos test showed a low value of hCG followed by a
5 test from another laboratory a few days later with a very high value, this would tend to show
6 that the Theranos test was wrong absent some other explanation,” *id.*, suggesting that Dr.
7 Linnerson intends to testify about specific Theranos tests and patients. But the summary does
8 not indicate whether he will opine about any specific patients and fails to identify any
9 specific patients or Theranos tests that form the bases of his opinions—again prejudicing Ms.
10 Holmes’ ability to prepare to meet his potential testimony at trial.
- 11 • The summary for Dr. Szmuc states that he will testify that in 30 years of using Sonora Quest,
12 he never questioned its results. Saharia Decl., Ex. A. at 3. To the extent this is an opinion
13 about whether Sonora Quest tests were inaccurate with respect to hCG, no basis of or reasons
14 for that opinion have been disclosed. The summary for Dr. Szmuc also discloses Dr.
15 Szmuc’s opinions about hypothetical tests. *See, e.g., id.* (“[I]f you have an hCG of 5,000 and
16 later one at 100,000, a next result below 5,000 indicates a problem with the test . . .”). If
17 this is intended to refer to actual Theranos tests of Dr. Szmuc’s patients, the summary does
18 not identify which tests or which patients.

19 Courts routinely exclude expert testimony when the government fails to disclose the bases and
20 reasons for the expert’s opinion. In *United States v. Valdez*, for example, the court excluded the
21 testimony of the government’s forensic expert regarding DNA testing of a bottle found in a stolen
22 government vehicle because the government’s summary of that expert testimony was deficient. 2019
23 WL 539074, at *2 (N.D. Cal. Feb. 11, 2019). The summary stated that the expert would (1) opine that
24 the DNA profiles on the bottle and the defendant were the same; (2) “explain the testing methods” used
25 to extract DNA from the stolen vehicle and the defendant; (3) explain the methods used to compare the
26 DNA samples; and (4) testify about the methods used for statistical analysis of DNA evidence in general

1 and as applied to the case. *Id.* The Court excluded the testimony, labeling the descriptions in the
 2 summary “mere generalities,” because the summary did not explain what the expert’s methods actually
 3 were. *Id.* Therefore, the Court held, the government’s “barebones disclosures” fell well short of the
 4 standards in Rule 16. *Id.*

5 The government’s summaries here provide even less detail. For example, the witnesses
 6 purportedly will opine that they have never had issues with other laboratories. Although the disclosures
 7 do not define what the witnesses mean by “problems,” presumably the government intends to use this
 8 testimony to suggest that other laboratories’ test results were accurate while Theranos’ were not. The
 9 summaries do not identify what methodologies the experts applied to arrive at those opinions, or how
 10 they came to those conclusions. If those conclusions are based purely on their failure to question other
 11 results, such opinions would be appropriately subject to a *Daubert* challenge. If they are based on
 12 research, a study, or a review of the expert’s patient records, Ms. Holmes is entitled to notice of that fact
 13 so that she can properly prepare to address the expert’s opinion either by motion or by cross-
 14 examination. Likewise, the government does not identify the test results on which the medical
 15 professionals are basing their conclusions about Theranos’ tests, rendering Ms. Holmes unable to probe
 16 the accuracy of their assertions or, potentially, to take discovery regarding other possible reasons for the
 17 test results. The current disclosures are “insufficient to allow counsel to frame a *Daubert* motion or
 18 other *motion in limine*, to prepare for cross-examination, or to allow a possible counter-expert to meet
 19 the purport of the case-in-chief testimony.” *Cerna*, 2010 WL 2347406, at *4; *see also id.* at *8 n.8 (“it
 20 is important to know the foundation for each specific opinion provided by an expert.”).

21 The Court should exclude the evidence, or in the alternative compel disclosure. Fed. R. Crim. P.
 22 16(d)(2). The disclosure by the government must allow, among other things, the defense adequately to
 23 “frame a *Daubert* motion [for these witnesses and] to prepare for cross-examination.” *Cerna*, 2010 WL
 24 2347406, at *4. Accordingly, if the Court decides that an order compelling disclosure is warranted, the
 25 disclosure should at a minimum provide: (1) an explicit opinion for each Theranos test referenced in
 26 each witness’s summary; (2) the specific patients and test results on which the witnesses are basing their
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1 opinions; (3) bases of and reasons for their conclusions that such test results were inaccurate or
2 unreliable; and (4) the bases of and reasons for their opinions regarding the accuracy of other
3 laboratories' tests. *See id* (providing explicit instructions to the government regarding the content of the
4 summaries ordered by the Court).

5 **CONCLUSION**

6 The Court should exclude the at-issue testimony of these experts, or else compel the government
7 to supplement its disclosures by August 11, 2020. *See* Fed. R. Crim. P. 16(d)(2).
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9

10 DATED: July 2, 2020

Respectfully submitted,

12 /s/ Amy Mason Saharia

13 KEVIN DOWNEY

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CERTIFICATE OF SERVICE

I hereby certify that on July 2, 2020, a copy of this filing was delivered via ECF on all counsel of record.

/s/ Amy Mason Saharia
AMY MASON SAHARIA
Attorney for Elizabeth Holmes